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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,017	08/01/2006	Teiko Sutoh	30162/41537	4672
4743 7590 10/26/2010 MARSHALL, GERSTEIN & BORUN LLP 233 SOUTH WACKER DRIVE 6300 WILLIS TOWER CHICAGO, IL 60606-6357			EXAMINER MCKANE, ELIZABETH L.	
			ART UNIT 1773	PAPER NUMBER
			NOTIFICATION DATE 10/26/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@marshallip.com

Office Action Summary

Application No.

10/551,017

Applicant(s)

SUTOH ET AL.

Examiner

ELIZABETH L. MCKANE

Art Unit

1773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,7 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,7 and 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 7, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel (WO 00/61200) in view of Kirckof (US 6,488,890).

Patel teaches a plasma sterilization indicator including an adsorption indicator (page 9, lines 5-9) and an organic metal compound (page 12, lines 10-26). Furthermore, Patel discloses that a product is formed in a reaction between the adsorption indicator and the activator (metal compound), which product discolors into a definitely different color change. See page 12, lines 10-13 wherein Patel teaches that the activator produces a reactive species in the presence of the plasma or hydrogen peroxide which reacts with the indicator to form a colored compound. Patel further discloses that the plasma atmosphere causes a change in pH (see Table 1). In use, an article is placed within a container to which is affixed the indicator. See page 3, lines 21-23 and lines 29-34; page 4, lines 33-34. Patel is silent with respect to the incorporation of a polyvalent alcohol in the indicator but does teach that the inks can be 'solvent based' (page 16, lines 19-20) and/or formulated in the form of ink formulations (col.15, line 10). Kirckof teaches a plasma sterilization indicator composition that can be applied to substrates using known printing processes such as ink jet printing. The composition includes a dye(s), water, and glycol solvents. See Tables 7a and 7b. The

glycol solvents used are ethylene glycol and diethylene glycol. See Example 7. It would have been obvious to one of ordinary skill in the art to use a water-soluble polyol as the 'alcohol' of Patel, since Kirckof evidences its use in plasma sterilization indicator ink compositions. The results of using a known polyol solvent in the ink formulation of Patel would have been readily apparent and expected.

Patel further discloses that the adsorption indicator may be hematoxylin (page 10, line 23), eriochrome black T (page 10, line 17), or pyridazo naphthol (page 11, line 14) and that the organic metal compound may be an aluminum chelate compound (aluminum acetylacetonate). See page 12, line 31. It is well-within the purview of one of ordinary skill in the art to choose from the indicators and activators disclosed by Patel to achieve the desired outcome, depending upon the chosen sterilant for the plasma, as well as the humidity, temperature, and time for sterilization. Furthermore, as the adsorption indicator of Patel is the same as that claimed in instant claim 2, it is an indicator that is capable of the "detection of metal ions that discolor as adsorbed on colloidal particles."

3. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Patel in view of Kirckof as applied to claim 10 above, and further in view of Schmidt et al. (US 2002/01552240).

The combination of Patel with Kirckof discloses using the glycol solvent in an amount of 20% for a chemical indicator ink to be used in an ink jet printer. See Tables 7a and 7b. Schmidt et al. teaches inks for use in an ink jet printer wherein polyvalent alcohol solvents such as dipropylene glycol, polyethylene glycol, and polypropylene

glycol are disclosed to be present in an amount of about 2-20%. See para [0013]-[0014]. Schmidt et al. further discloses that dipropylene glycol is preferred as it serves as a humectant and prevents clogging and plugging of ink jet nozzles. See para [0019]. Thus, it is deemed obvious to one of ordinary skill in the art to adjust the amount of organic solvent as necessary to achieve the desired properties of the ink, where such is readily determinable by routine experimentation.

Response to Arguments

4. Applicant's arguments filed 10 September 2010 have been fully considered but they are not persuasive.
5. On page 4 of the Response, Applicant submits that the reaction mechanism of the instant invention is different from that of Patel. The Examiner does not contend this point. However, Applicant is reminded that the instant claims are article claims, not method claims. As the indicator of Patel employs the same organic metal compound and adsorption indicator, it meets the claim limitations.
6. Furthermore, although Applicant argues that Patel does not disclose "one or more compounds (A) selected from the group consisting of adsorption indicators...wherein the adsorption indicator is selected from indicators used in the detection of metal ions that discolor as adsorbed on colloidal particles," the Examiner submits that Patel does indeed teach these adsorption indicators. In fact, Patel teaches the use of hematoxylin (page 10, line 23), eriochrome black T (page 10, line 17), or pyridazo naphthol (page 11, line 14). It is immaterial that the adsorption indicators are

used in a manner different from that of the instant invention as the instant claims are directed to an article *not* a method of use.

7. Continuing on page 5 of the Response, Applicant argues that the color change mechanisms of the present invention is entirely different from that of Patel. However, the claims require only a product formed in a reaction between at least one compound (A) and the organic metal compound (B) discolors into a definitely different color in a particular pH range due to a pH change. As set forth in the rejection *supra*, this is precisely what Patel teaches on page 12.

8. Moreover, although Applicant notes that in Patel the reactive species are bromine anions wherein in the present invention the reactive specie is a cation, the instant claims do not require a particular ion as the reactive species.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH L. MCKANE whose telephone number is (571)272-1275. The examiner can normally be reached on Mon-Fri; 5:30 a.m. - 2:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth L McKane/
Primary Examiner, Art Unit 1773

elm
21 October 2010

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